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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,266	12/15/2003	Michael John Rutter	CHM-009	3842

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CINCINNATI, OH 45249

EXAMINER

DIXON, ANNETTE FREDRICKA

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/736,266	Applicant(s) RUTTER, MICHAEL JOHN	
	Examiner Annette F. Dixon	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7-12,16,17 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 7-12, 16, 17, 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>Oct 12, 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "20c" has been used to designate both shank and heat-staking end. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The use of the trademark "Silastic" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

3. Specifically, Applicant uses the phrase "Dow Corning Silastic, medical grade" and "silastic diaphragm". Applicant's recitation of "Dow Corning Silastic, medical grade"

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appears to be a recitation of the trademark material, while "silastic diaphragm" appears to be more of a recitation of the concept of a material having properties of silicone and plastic. Examiner requests Applicant further clarify and take caution in the use of trademarks and provide generic terminology.

Claim Objections

4. **Claim 3** is objected to because of the following informalities: Examiner is unsure if the Applicant would like to be consistent in the recitation of the diaphragm's characteristics by including the limitation of the "low-modulus" silicone sheet material as Applicant has done in **Claims 9 and 22**. Appropriate correction and clarification is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **Claims 1, 3, 4, 7-12, 16, 17, 21-25** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No amendment may

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introduce new matter into the disclosure of an application after its filing date. See MPEP §608.04.

7. Specifically, **Claims 1, 10, 11, 21, 23, and 25** now recite the claim limitation of the second valve unit begins to open when the intrathoracic pressure during expiration is "*greater than*" about # cm of water or "beyond" # cm of water (**Claim 25**); however, the originally filed disclosure does not provide evidence that Applicant possessed the newly claimed invention at the time the application was filed. In fact, the original specification of the instant invention discloses, "...reaches about 3 cm of water" (Page 12 – paragraph 0045), "...of about 4 cm of water" (Page 4 – paragraph 0020), and "...reaches about 4 cm of water" (Page 9 – paragraph 0036, and Page 12 – paragraph 0045). The recitation of "about" gives way to the second valve unit to open at 2.5 cm of water and 3.3 cm of water; while the recitation of greater than limits the opening of the second valve unit to only operate at pressure 3.0 cm of water and greater. There is no specific recitation or support for the second valve unit opening at "*greater than*" about 3 cm of water or "beyond" # cm of water (**Claim 25**) in the original disclosure; and therefore, the subject matter added to the independent **Claims 1 and 21**, as well as their dependants (**Claims 3, 4, 7-12, 16, 17, 22-25**) is considered new matter and must be cancelled from the claims. Appropriate correction and clarification is required.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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9. **Claims 1, 3, 4, 7-12, 16, 17, 21-25** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Specifically, **Claims 1, 10, 11, 21, 23, 11** now recite the claim limitation of the second valve unit blocks airflow when the intrathoracic pressure during expiration is "less than about 3 cm of water" (Page 4 – paragraph 0018) or "less than about 4 cm of water" (Page 4 – paragraph 0020). As a result of these two separate and distinct limitations, the scope and operational characteristics of the second valve are inherently broad and conflict in nature. Appropriate correction and clarification is required.

11. Specifically, **Claims 1, 7, 12, 16, 17, 21, 23-25** now recite the claim limitation directed only towards the second valve consisting of a slit valve or the second valve consisting of an umbrella valve. **Claims 1 and 21** recite "...intrathoracic pressure during expiration is ...3 cm of water", this limitation is only supported by the umbrella valve (Page 12 – paragraph 0045); therefore, the recitation of **Claims 7, 10, 11, 12, 16, 17, 21, 23-25** is improper for reciting limitations of a slit valve. **Claims 10, 11, 12, 16, 17, 23-25** recite the valve is "fully open when the intrathoracic pressure reaches about 10 cm of water", this limitation of "fully open at about 10 cm of water" is only supported by the slit valve (Page 9 – paragraph 0036); therefore, the recitation of these dependant claims to have limitations associated with umbrella valve found in the independent **Claims 1 and 21** is improper. To reiterate, Applicant has disclosed the slit valve to begin to open at about 4 cm of water and is fully open at about 10 cm of water (Page 9 – paragraph 0036); while the umbrella valve begins to open at about 3 cm of water or

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about 4 cm of water, depending on the embodiment, and the valve is fully open at about 12 cm of water, typically about 10 cm of water (Page 12 – paragraph 0045). The recitation of when the valve is “fully open” is separate and distinct as the umbrella valve may or may not be open at 10 cm of water. Further, Examiner is unsure of Applicant’s recitation in **Claims 7, 12, 17, and 21** of the slit valve and umbrella valve to be functional equivalents by the use of the word “or”, when Applicant has provided a disclosure that provides separate and distinct limitations that are exclusive to slit and umbrella valves. (Page 9 – paragraph 0036, and Page 12 – paragraph 0045). Appropriate correction and clarification is required.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



AFD

September 5, 2006



Henry Bennett
Supervisory Patent Examiner
Group 3700